

WE CLAIM:

1. An aqueous nasal spray composition comprising a therapeutically effective amount of a medicament<sup>a</sup> and an aqueous carrier comprising from 0.50 to 15.00% by weight/volume of a water soluble polymer selected from the group consisting of polyvinylpyrrolidone and mixtures thereof.<sup>b</sup>
2. An aqueous nasal spray composition comprising of an effective amount of a medicament in an aqueous carrier comprising:
- 0.50 to 15.00% by weight/volume of a water soluble polymer selected from the group consisting of polyvinylpyrrolidone and mixtures thereof;
  - 0.00 to 15.00% by weight/volume of polyethylene glycol;
  - 0.00 to 10.00% by weight/volume of a moisturizing agent or mixtures of moisturizing agents;
  - 0.00 to 10.00% by weight/volume of an antioxidant;
  - 0.001 to 0.10% by weight/volume of an antimicrobial preservative;
  - 0.00 to 5.00% by weight/volume of an aromatic alcohol;
  - a sufficient amount of a pharmaceutically acceptable buffer to maintain the pH of the composition within the range of about 4.0 to 8.0 and
  - QS water.
3. The aqueous nasal spray composition of claim 2 comprising of an effective amount of a medicament in an aqueous carrier comprising:

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- 0.50 to 2.5% by weight/volume of a  
water soluble polymer selected from the  
group consisting of polyvinylpyrrolidone  
and mixtures thereof;
- 5 0.5 to 10.00% by weight/volume of polyethylene  
glycol;
- 1.00 to 4.00% by weight/volume of a moisturizing  
agent;
- 10 0.01 to 0.05% by weight/volume of an  
antioxidant;
- 0.02 to 0.025% by weight/volume of an  
antimicrobial preservative;
- 0.20 to 3.00% by weight/volume of an aromatic  
alcohol;
- 15 a sufficient amount of a pharmaceutically  
acceptable buffer to maintain the pH of the  
composition within the range of about 4.0 to  
8.0 and
- 20 QS water.
4. The aqueous nasal spray composition of claim 2  
comprising of an effective amount of a medicament in an  
aqueous carrier comprising:
- 25 1.00 to 1.50% by weight/volume of a  
water soluble polymer selected from the  
group consisting of polyvinylpyrrolidone  
and mixtures thereof;
- 2.5 to 5.00% by weight/volume of polyethylene  
glycol;
- 30 1.50 to 3.50% by weight/volume of a moisturizing  
agent or mixtures of moisturizing agents;
- 0.015 to 0.030% by weight/volume of an  
antioxidant;

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0.02 to 0.025% by weight/volume of an  
antimicrobial preservative;  
0.25 to 1.00% by weight/volume of an aromatic  
alcohol;  
5 a sufficient amount of a pharmaceutically  
acceptable buffer to maintain the pH of the  
composition within the range of about 4.0 to  
8.0 and  
QS water.

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5. The aqueous nasal spray composition of claim 2  
wherein the moisturizing agent is propylene glycol; the  
antioxidant is disodium EDTA; the antimicrobial preservative  
is benzalkonium chloride; and the aromatic alcohol is benzyl  
15 alcohol; and the buffer is a phosphate buffer.

6. The aqueous nasal spray composition of claim 5  
wherein the medicament is selected from the group consisting  
of chlorpheniramine maleate, oxymetazoline hydrochloride  
20 and mixtures thereof.

7. The aqueous nasal spray composition of claim 6  
wherein the medicament is oxymetazoline hydrochloride.

25 8. The aqueous nasal spray composition of claim 6  
wherein the medicament is chlorpheniramine maleate.

9. The aqueous nasal spray composition of claim 2  
which comprises:

30

INGREDIENTS

% Wt/Vol

Water

QS

Disodium EDTA

0.0200

≠ Sodium Phosphate Dibasic

0.0975

≠ Sodium Phosphate Monobasic

0.5525

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check on  
abbreviation  
in MPEP  
5 or FP

PVP K-90	0.2500
PVP K-30	1.0000
PEG 1450	2.5000
Benzyl Alcohol	0.2500
Benzalkonium Chloride (17% solution)	0.0200
Chlorpheniramine Maleate	0.5000
Oxymetazoline Hydrochloride	0.0500

10. The aqueous nasal spray composition of claim 2  
10 which comprises:

	<u>INGREDIENTS</u>	<u>% Wt/Vol</u>
	Water	QS
	Disodium EDTA	0.0200
15	Sodium Phosphate Dibasic	0.0975
	Sodium Phosphate Monobasic	0.5525
	PVP K-90	0.2500
	PVP K-30	1.0000
	PEG 1450	2.5000
20	Benzyl Alcohol	0.2500
	Benzalkonium Chloride (17% solution)	0.0200
	Oxymetazoline Hydrochloride	0.0500

11. The aqueous nasal spray compositions of claim 2  
25 which comprises:

	<u>INGREDIENTS</u>	<u>% Wt/Vol</u>
	Water	QS
	Disodium EDTA	0.0200
30	Sodium Phosphate Dibasic	0.0975
	Sodium Phosphate Monobasic	0.5525
	PVP K-30	3.0000
	PEG 600	5.0000
	Benzyl Alcohol	0.2500

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Benzalkonium Chloride (17% solution)	0.0200
Oxymetazoline Hydrochloride	0.0500
Chlorpheniramine Maleate	0.5000

- 5 12. The aqueous nasal spray composition of claim 2  
which comprises:

	<u>INGREDIENTS</u>	<u>% Wt/Vol</u>
	Water	QS
10	Disodium EDTA	0.0200
	Sodium Phosphate Dibasic	0.0975
	Sodium Phosphate Monobasic	0.5525
	PVP K-30	3.0000
	PEG 1450	5.0000
15	Benzyl Alcohol	0.2500
	Benzalkonium Chloride (17% solution)	0.0200
	Oxymetazoline Hydrochloride	0.0500
	Chlorpheniramine Maleate	0.5000

- 20 13. The aqueous nasal spray composition of claim 2  
which comprises:

	<u>INGREDIENTS</u>	<u>% Wt/Vol</u>
	Water	QS
25	Disodium EDTA	0.0200
	Sodium Phosphate Dibasic	0.0975
	Sodium Phosphate Monobasic	0.5525
	PVP K-90	0.1000
	PVP K-30	3.0000
30	PEG 1450	2.5000
	Propylene glycol	0.2500
	Benzalkonium Chloride (17% solution)	0.1471
	Oxymetazoline Hydrochloride	0.0500

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14. The aqueous nasal spray composition of claim 2 which comprises:

	<u>INGREDIENTS</u>	<u>% Wt/Vol</u>
5	Water	QS
	Disodium EDTA	0.0200
	Sodium Phosphate Dibasic	0.0975
	Sodium Phosphate Monobasic	0.5525
10	PVP K-90	0.1000
	PVP K-30	3.0000
	PEG 1450	5.0000
	Propylene Glycol	2.0000
	Glycerin	0.1000
15	Benzalkonium Chloride (17% solution)	0.1471
	Oxymetazoline Hydrochloride	0.0500

add  
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